mHealth Sensors, devices & APPs
ADVOCACY for ACCURACY

The difference between medical device and a consumer device &
Importance of mobile health data for the Healthy Aging ecosystem

Johan Goris
mobile health measuring devices,
risk & quality management,
medical device standardisation and certification

A meeting of the minds @
- Med-e-Tel – Luxembourg April, 2015

epposi Partnering for Healthcare Policy
PHR mobile DATA sources

- IoT
  - Public context sensors & Apps

- Smart Home
  - Sensors & Apps

- Ambient Assisted Living
  - Sensors & Apps

- Fitness Wellness
  - Sensors & Apps

- mHealth: Sensors & Apps

- Aggregated dataset IP

- Telemedicine: Medical Devices

- EHR

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PHR mobile DATA sources

> 1000 Sensors, Devices & APP’s
# The mobile prevention perspective

<table>
<thead>
<tr>
<th>Prevention type:</th>
<th>Primary</th>
<th>Secondary</th>
<th>Tertiary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health status</td>
<td>Robust</td>
<td>At risk</td>
<td>Diagnosed</td>
</tr>
<tr>
<td>Domain</td>
<td>Wellness/Fitness</td>
<td>mHealth BYOD</td>
<td>Telemedicine</td>
</tr>
<tr>
<td>Action</td>
<td>Healthy lifestyle promotion</td>
<td>Preventative self monitoring</td>
<td>+ Follow-up Monitoring</td>
</tr>
<tr>
<td>Acquisition</td>
<td>OTC</td>
<td>OTC</td>
<td>B2B</td>
</tr>
<tr>
<td>System</td>
<td>OUTSIDE</td>
<td>OUTSIDE</td>
<td>INSIDE</td>
</tr>
<tr>
<td>Privacy concern</td>
<td>?</td>
<td>+</td>
<td>++</td>
</tr>
<tr>
<td>Accuracy need</td>
<td>?</td>
<td>+</td>
<td>++</td>
</tr>
<tr>
<td>Regulatory</td>
<td>Consumer CE</td>
<td>↔ CE + Label ?</td>
<td>Medical device CE</td>
</tr>
<tr>
<td>Main Risk</td>
<td>Low health risk</td>
<td>Outcome risk</td>
<td>+ Safety risk</td>
</tr>
<tr>
<td>Why</td>
<td>Recreational use</td>
<td>False positives False negatives</td>
<td>+ Professional liability</td>
</tr>
</tbody>
</table>
Secondary prevention
= closing the tap for lifestyle related Chronic Diseases

Lack of ACCURACY leads to:

• False negatives
  => missed outcome of early detection

• False positives
  ➔ health anxiety ➔ overuse of limited HC resources
  or warning fatigue ➔ more false negatives
Stakeholders’ NEED for Accuracy

• Patient / Caregiver / HC Provider
  » Personal health data (primary use)
  » Decision making: Prevention <<< Diagnosis
  » TRUST & reliability

• Research
  » BIG DATA (secondary use) >< data cleaning cost!

• Payers / NHCS
  » Outcome => HCS’ sustainability

• MedTech Industry / Pharma Industry
  » Clinical investigations

• ALL:
  » Viability / Liability
mHealth ACCURACY aspects

• **Measurement** related accuracy (technical)
  - Sensor / electronics / software / readout
  - Mean Error & Standard Deviation compared to ...

• **Methodology** related accuracy
  - Validated methodology & performance
    - Good clinical practice (BHS/ ESH 2002-2010 / ... ) & Standards (AAMI/ IEC/ ...)
  - Parameter equivalence & digital health literacy
    - Skin vs Core Temperature :
      » Forehead / Wrist / Chest /... >< Esophageal / Timpanic / Axillary / Rectal / ....

• **Use** related accuracy & errors:
  - Lay user (consumer/patient + non-professional caregivers)
    - Usability / Human Engineering => SIMPLEXITY
    - (Digital) Health Literacy / Frailty => PERSONALISED TECHNOLOGY ...
  - vs Professional, trained caregivers
mHealth has great potential to support 2nd prevention but ... faces CHALLENGES to warrant positive outcome

Re-engineer the wheel?

• Classic HTA?
  negative outcome = predictable in casu “lack of ACCURACY”
  Full HTA on “accuracy untested” devices is a waste of time and resources

• Rapid mobile HTA
  • Sensors’ & APPs’ measurement ACCURACY FIRST
  • SAFETY before application
  • ...

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Regulatory GAP awareness

Regulatory

mHealth

Epossi.
Stakeholders

DATA
Intended Use

ACCURACY
driven

? Third party
Verification
Label?
Certification?

ACCURACY
assessment
during
rmHTA

OR

Medical CE
Notified Body
Vigilance
Inspection?

DEVICE
Intended Use

SAFETY
focus

Consumer CE
Certification
Vigilance
Inspection?

? Third party
Verification
Label?
Certification?

Clinicalley
validated
Methodology

Existing test
facilities

? Methodology

NEW test
facilities

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ACCURACY VALIDATION: HOW (not)?

- **Medical Device Regulation?**
  Concentrates on patient Risk, including performance, BUT:
  - accuracy is seldom (re-)verified during:
    - CE certification: Notified Bodies
    - Market Inspection: National Authorities

- **Deregulation?**
  - cfr FDA discretion on LOW RISK / wellness / SaMD / ...
    - INTENDED USE << Unintended Use & Obvious Use
  - Consumer Product Safety and Market Surveillance Regulation
    - claimed performance vs stakeholders needed accuracy?
    - Inspection or THIRD PARTY test & validation?

- **Labels / Standards**
  - Continua = Interoperability: Wireless & Data
  - IEEE PHD Agents = mainly conventional Medical focus? cNIBP ≠ NIBP

**NEED** for interoperability & “look alike” parameter differentiation
**NEED** for DATA SOURCE identification & traceability (mobile UDI)

- measurement origin / parameter / resolution / quantity / timestamp & zone / sampling rate / calibration date / ...
**METHODOLOGY & EVIDENCE**

- **Existing technology:** *eg* automated NIBP sphygmanometers
  - Standards (IEC80601-2-30)
  - Existing SIMULATORS for field performance testing
  - Technical evidence: validated methodology & accuracy (BHS / ESH)
  - Clinical evidence

- **New methodology:** *e.g.* cuffless NIBP
  - Standards (idem as above? OR IEEE 1708:2014)
  - new test-methods / SIMULATORS to be developed?
  - No technical evidence (accuracy to be validated BHS / ESH)
  - Clinical evidence: idem as above if validated

- **New parameters:** *e.g.* Calories burned
  - NO specific standardised testing methods or SIMULATORS
  - NO technical evidence: required accuracy for valuable data?
  - NO clinical evidence: Intended Use: Vital sign / context?
mHEALTH ACCURACY SOLUTIONS

• Consumer (Auto) Regulation of mHealth?
  – ACCURACY assessment & validation
  – Registration & Unique Device Identification (mobile UDI)
    • Vigilance & Tracability
  – Restrictive LABELS for sub optimal accuracy?
    • cfr BHS : categories A/B/C/D for Blood Pressure Meters
    • “RECREATIONAL” => “not accurate for prevention or early diagnosis”

• Funding the GAPS
  Rapid mobile HTA for SME’s (Multi stakeholder MATRIX methodology)
  Early detection of systemic inaccuracy
  STOP funding more square wheels
    ⇒ Viable innovation >>> Product hype
    ⇒ Solution maturity >>> a sensor with an APP

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• Promote DIGITAL HEALTH LITERACY
  – mHealth Information Platform
    • Sensors & Apps : Technical + Usability
    • Valuable information for all Healthcare Stakeholders
      » Consumers - patients - family
      » HCP’s / Caregivers / Payers / Policy makers / Investors/ ...

e.g. Aggregated information from:

  Med-Q : Evaluated database of + 1200 mHealth Sensors & APPs
  Patient-View : Apps recommended by healthcare communities
  dmdSanté: Apps recommended by healthcare professionals
  ...

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ACCURACY

GAP to fill